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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,939	04/19/2001	Michael J. Delwiche	2307O-115710	5257

20350 7590 09/29/2003

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EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/839,939	DELWICHE ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-14 and 16-20 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4/19/01</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claims 11–20 are pending and are considered on the merits.

INDEFINITE

Claims 12 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites “wherein the biological fluid is blood or urea”. Urea is not a biological fluid. Thus the claim is indefinite. Further, there is no antecedent basis for “the biological fluid”.

Claim 19 recites “the prediction error” which is not a term of art. Is this a standard deviation from the mean or some other art appreciated measurement of error?

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States,

Claims 11 and 12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 4,073,694 [A] or US 4,440,620 [B] or Oehler *et al.* [U].

The claims are directed to a method of analyzing a component from a liquid test sample which is a product of an enzymatically catalyzed process comprising:
contacting the test sample with either an enzyme or a substrate wherein the contacting forms carbonate ion in equilibrium with CO₂,
detecting the CO₂.

The references are relied upon as explained below.

US 4,073,694 discloses a method to measure an antibiotic in blood comprising:
contacting the blood with a source of urease,
measuring the evolved CO₂. See Figures 1–3.

US 4,440,620 discloses a method for measuring urea in blood (col. 6, l. 49) comprising:
contacting the blood with urease immobilized on a membrane (col. 7, l. 7),
which forms an equilibrium with dilute sodium bicarbonate (col. 7, l. 42)
and the CO₂ is detected by measuring a change in pH.

Oehler *et al.* disclose a method of detecting gases produced by biological systems with an enzyme–photoacoustic sensor. The biological catalyst, such as urease, is immobilized directly onto the gas–permeable membrane and the partial pressure of the gas, such as carbon dioxide formed from the reaction of urea with the immobilized urease, is measured, see article.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13, 17–20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,440,620 [B] taken with Gonda *et al.* [V].

The claims are directed to a method of analyzing urea nitrogen in milk comprising:
contacting a milk sample with urease, wherein an equilibrium forms between the carbonate ion and CO₂,
shifting the equilibrium,
detecting the CO₂.

The references are relied upon as explained below.

US 4,440,620 has been discussed above and is directed to the detection of urea in a liquid to be inspected (claim 1, col. 1, l3).

Gonda *et al.* teach that urea is present in blood, milk and urine of dairy cows, and that detection of urea in these fluids is of interest in the dairy industry.

The use of the method disclosed in US 4,440,620 for the detection of urea in milk would have been obvious when taken with Gonda *et al.* who teach that urea content of milk is of interest in the dairy industry. Although the reference is silent with regard to the "prediction error", the error of the reference is assumed to be the same as the error limitation in the claim, in the absence of persuasive evidence to the contrary. The Patent and Trademark Office is not equipped to perform experiments. It is further considered that agitating the sample is well within the purview of one of skill in the art in the absence of unexpected results.

Claims 13, 14, 16–20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuhrmann *et al.* [W] in view of Gonda *et al.* [V].

The claims have been discussed above.

Fuhrmann *et al.* disclose a method for determining carbon dioxide formed by the catalysis by urease from urea in a solution. An

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ultrafiltration membrane protects the immobilized urease when real world samples are run (p. 656). The bicarbonate-carbon dioxide equilibrium is shifted towards carbon dioxide (p. 658). The fluid is pumped through the chamber and is, thus agitated (Fig. 5). The carbon dioxide is separated through a gas permeable membrane prior to detection and is, thus, measured in the vapor phase.

Gonda *et al.* teach that urea is present in blood, milk and urine of dairy cows, and that detection of urea in these fluids is of interest in the dairy industry.

The use of the method disclosed in Fuhrmann *et al.* for the detection of urea in milk would have been obvious when taken with Gonda *et al.* who teach that urea content of milk is of interest in the dairy industry. Although the reference is silent with regard to the "prediction error", the error disclosed in the reference (an accuracy of 97.4%, Fig. 6) of the reference is assumed to be the same as the error limitation in the claim, in the absence of persuasive evidence to the contrary. The Patent and Trademark Office is not equipped to perform experiments. Correlating the amount of carbon dioxide produced from urease to the amount of urea in the initial sample is a well known stoichiometric relationship, see Table 1.

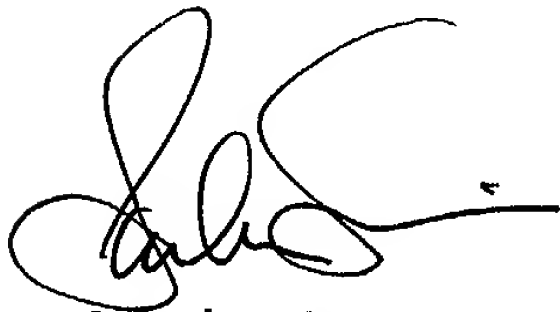
One of ordinary skill in the art would have been motivated at the time of invention to make this substitution of urea containing samples in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Allowable Subject Matter

Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a stylized flourish extending to the right.

Sandra Saucier
Primary Examiner
Art Unit 1651
September 22, 2003